Functional Specifications Preparing the Buffer

| Name / Project Role | Signature | Date |
|---------------------|-----------|---------------|
| | | (dd/mmm/yyyy) |
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1. INTRODUCTION

The goal of this document is to describe the IS teams interpretation of the requirements, and describes the proposed functionality to be delivered.

1.1. Glossary

This section defines specific project/system term and acronym that could be used on this document.

| Term or Acronym | Definition |
|-----------------|------------|
| N/A | N/A |

2. BLOCK IDENTITY CARD

| Name | Version | Description |
|------|---------|----------------------|
| XAWT | V1 | Preparing the Buffer |

3. BLOCK INPUT VARIABLES

| Input Variable | | | | |
|---------------------------|--------------------------|---------------------------|--|--|
| Variable Name | Data Type | Description | | |
| Equipment identification | Equipment identification | Equipment identification | | |
| Equipment Allocation | Equipment Allocation | Equipment Allocation | | |
| Status of equipment (GMP) | Text | Status of equipment (GMP) | | |
| Instruction | Text | Instruction | | |
| GMP Status of complaint | List | GMP Status of complaint | | |
| equipment | | equipment | | |
| GMP Date of compliant | Date | GMP Date of compliant | | |
| equipment | | equipment | | |
| File review completed | List | File review completed | | |

4. BLOCK DETAILED SPECIFICATION

4.1 Design description

| ID | Detailed description |
|--------|--|
| CBF001 | System displays the equipment identification. "FRM0001" description is "Before manufacturing begins, perform the following checks on the equipment used (EQP001, EQP002, EQP003 and EQP004)". Formula type activity with formula: [Equipment identification "variable" EQPCHK] |
| | 2. System displays the status of equipment (GMP). "FRM0002" description is "Before manufacturing begins, ensure that items related to the manufacturing of the previous batch (absence of raw materials/consumables, absence of documents, absence of labels, absence of samples, absence of small dirty equipment) have been removed from the work area for manufacturing". Formula type activity with formula: [Text "variable" GMPSTS] |
| | 3. System displays the qualification/calibration status check of equipment. "FRM0003" description is "Qualified/calibrated equipment". Formula type activity with formula: [List "variable" QLFCAL] |
| | 4. System displays the GMP status of compliant equipment. "FRM0004" description is "Status of equipment authorized for GMP use". Formula type activity with formula: [Date "variable" GMPDAT] |
| | 5. System displays the file review completed. "FRM0005" description is "File review completed AND buffer accepted". Formula type activity with formula: [List "variable" FILREV] |